CLAIMS

The current claim set of the application is presented below. Indications as to the status of the claims ("original", "currently amended", "cancelled", "new", etc.) appear in parentheses after the claim number. Deletions are identified in bold with double brackets and strikethrough (e.g. **[[~~deletion~~]]**) and new text is identified in bold with underlining (e.g. **new matter**).

1. (Amended) A~~n~~ sterile injectable pharmaceutical composition comprising gabapentin and a pharmacologically acceptable solvent, wherein the gabapentin is present in the solution at a concentration greater than about 30 mg/mL, and wherein the solution has a tonicity of less than about 900mOsm.

2. (Original) The injectable composition of claim 1, wherein the composition is an injectable solution.

3. (Original) The injectable composition of claim 2, wherein the solution comprises greater than about 31 mg/ml gabapentin.

4. (Original) The injectable composition of claim 2, wherein the solution comprises greater than about 32 mg/ml gabapentin.

5. (Original) The injectable composition of claim 2, wherein the solution comprises greater than about 33 mg/ml gabapentin.

6. (Original) The injectable composition of claim 2, wherein the solution comprises greater than about 34 mg/ml gabapentin.

7. (Original) The injectable composition of claim 2, wherein the solution comprises greater than about 35 mg/ml gabapentin.

8. (Original) The injectable composition of claim 2, wherein the solution comprises greater than about 36 mg/ml gabapentin.

9. (Original) The injectable composition of claim 2, wherein the solution comprises greater than about 37 mg/ml gabapentin.

10. (Original) The injectable composition of claim 2, wherein the solution comprises greater than about 38 mg/ml gabapentin.

11. (Original) The injectable composition of claim 2, wherein the solution comprises greater than about 39 mg/ml gabapentin.

12. (Original) The injectable composition of claim 2, wherein the solution comprises greater than about 40 mg/ml gabapentin.

13. (Original) The injectable composition of claim 2, wherein the solution comprises between about 30 mg/mL and about 100 mg/mL gabapentin.

14. (Original) The injectable composition of claim 13, wherein the solution comprises between about 30 mg/mL and about 90 mg/mL gabapentin.

15. (Original) The injectable composition of claim 14, wherein the solution comprises between about 40 mg/mL and about 90 mg/mL gabapentin.

16. (Original) The injectable composition of claim 15, wherein the solution comprises about 80 mg/mL gabapentin.

17. (Original) The injectable composition of claim 2, wherein the solvent is water.

18. (Original) The injectable composition of claim 17, further comprising sodium chloride.

19. (Original) The injectable composition of claim 18, wherein the solution comprises sodium chloride in an amount such that the solution is substantially isotonic with cerebrospinal fluid.

20. (Original) The injectable composition of claim 2, wherein the tonicity of the solution is in the range of about 250 mOsm to about 700 mOsm.

21. (Original) The injectable composition of claim 2, wherein the tonicity of the solution is in the range of about 250 mOsm to about 600 mOsm.

22. (Original) The injectable composition of claim 2, wherein the tonicity of the solution is about 500 mOsm.

23. (Original) The injectable composition of claim 2, wherein the solution has a pH between about 4 and about 9.

24. (Original) The injectable composition of claim 23, wherein the solution has a pH between about 5 and about 7.

25. (Original) The injectable composition of claim 2, wherein the solution comprises substantially no preservatives.

26. (Original) The injectable composition of claim 2, wherein the solution comprises substantially no buffers.

27. (Original) The injectable composition of claim 1, further comprising one or more additional therapeutic agents.

28. (Original) The injectable composition of claim 27, wherein at least one of the one or more additional therapeutic agents is selected from the group consisting of: a local anesthetic, a GABA agonist, a serotonin agonist, a thyrotropin-releasing hormone, a benzodiazapine, an opioid agonist, a non-steroidal anti-inflammatory agent, an alpha2-adrenergic agonist, an anticonvuslant agent, and an antidepressant.

29. (Original) The injectable composition of claim 27, wherein at least one of the one or more additional therapeutic agents is selected from the group consisting of: morphine, hydromorphone, bupivacaine, clonidine, lidocaine, baclofen, muscimol, sumatriptan, sodium valproate, midazolam, adenosine and alprazolam, or a pharmacologically acceptable salt thereof.

30. (Original) The injectable composition of claim 29, wherein the composition comprises morphine or a pharmacologically acceptable salt thereof.

31. (Original) The injectable composition of claim 30, wherein the composition comprises between about 10 mg/mL and about 50 mg/mL of the morphine or the pharmacologically acceptable salt thereof.

32. (Original) The injectable composition of claim 29, wherein the composition comprises hydromorphone or a pharmacologically acceptable salt thereof.

33. (Original) The injectable composition of claim 32, wherein the composition comprises between about 1 mg/mL to about 20 mg/mL of the hydromorphone or the pharmacologically acceptable salt thereof.

34. (Original) The injectable composition of claim 16, wherein the composition has a pH between about 5.5 and 6.5, has a tonicity of about 500 mOsm, and comprises substantially no preservatives and substantially no buffers.

35. (Original) A kit comprising the injectable composition of claim 1 and instructions indicating that the solution may be administered to a subject's cerebrospinal fluid.

36. (Original) The kit of claim 35, wherein the instructions indicate that the composition may be administered intrathecally.

37. (Original) The kit of claim 35, wherein the instructions further indicate that the composition may be placed in an implantable pump system.

38. (Original) An injectable solution comprising gabapentin and a solvent, wherein the solution comprises less than 0.9% (w/v) sodium chloride.

39. (Original) The solution of claim 38, wherein the solution comprises greater than about 30 mg/ml gabapentin.

40. (Original) The solution of claim 39, wherein the solution comprises between about 30 mg/ml and about 100 mg/ml gabapentin.

41. (Original) The solution of claim 40, wherein the solution comprises about 80 mg/ml gabapentin.

42. (Original) The solution of claim 38, further comprising one or more additional therapeutic agents.

43. (Original) The solution of claim 42, wherein at least one of the one or more additional therapeutic agents is selected from the group consisting of:
a local anesthetic, a GABA agonist, a serotonin agonist, a thyrotropin-releasing hormone, a benzodiazapine, an opioid agonist, a non-steroidal anti-inflammatory agent, an alpha2-adrenergic agonist, an anticonvuslant agent, and an antidepressant.

44. (Original) The solution of claim 42, wherein at least one of the one or more additional therapeutic agents is selected from the group consisting of: morphine, hydromorphone, bupivacaine, clonidine, lidocaine, baclofen, muscimol, sumatriptan, sodium valproate, midazolam, adenosine and alprazolam, or a pharmacologically acceptable salt thereof.

45. (Original) The solution of claim 44, wherein at least one of the one or more additional therapeutic agents is selected from the group consisting of morphine and hydomorphone, or a pharmacologically acceptable salt thereof.

46. (Original) A process for preparing an injectable gabapentin composition, the process comprising:
mixing gabapentin in a diluent to form a fluid composition;
determining the tonicity of the fluid composition; and
adding a tonicity enhancing agent to the fluid composition if the tonicity of the fluid composition is determined to be less than between about 290 mOsm to about 320 mOsm.

47. (Original) The process of claim 46, wherein the tonicity enhancing agent is added to adjust the tonicity of the fluid composition to between about 290 mOsm to about 320 mOsm.

48. (Original) The process of claim 46, wherein no tonicity enhancing agent is added to the fluid composition if the tonicity of the fluid composition is determined to be greater than between about 290 mOsm to about 320 mOsm.

49. (Original) The process of claim 46, wherein one or more additional therapeutic agents are added to the fluid composition prior to determining the tonicity of the fluid composition.

50. (Original) The process of claim 46, wherein the pH of the fluid composition is adjusted prior to determining the tonicity of the fluid composition.

51. (New) The composition of claim 1, wherein sterilization of the composition comprises heat-treatment.